Question Paper

Exam Date & Time: 02-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Quality Assurance
MPharm Semester -II End-Semester Examination May 2019
Date : 02/05/2019

Hazards and Safety Management [PQA-MQA201T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Describe the steps to be considered in establishing the hierarchy of hazard control with examples. (10)

2) Explain the threats to natural resources. (10)

3) Explain the applicable instrumental methods in analysis of trace contaminants in an effluent. (10)

4) List the applications of TLC Concept. (10)

5) Analyse the stages of preliminary hazard analysis. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Mention the class of fire and justify the choice of extinguisher to be used in case of following fire accidents:
i) LPG Gas explosion at pharma warehouse
ii) Fire at office. (5)

7) Why are natural resources are so important to us? (5)

8) How some renewable energy resources are threat to living beings on the earth? (5)

9) Analyse the harmful effects of Chlorination reactions and sulphonating agents (5)

10) List the indications for the oxygen therapy. (5)

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Question Paper

Exam Date & Time: 04-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Quality assurance
MPharm Semester II - End-Semester Examination May 2019
Date : 04/05/2019

Pharmaceutical Validation [PQA-MQA202T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Describe important factors to be considered for tablet process validation. (10)

2) Explain mechanical calibration and performance verification test for type 1 dissolution apparatus. (10)

3) Describe operational qualification and performance qualification of HPLC (10)

4) What is Validation master file? Explain its principle and contents for a pharmaceutical industry (10)

5) Analyse the parameters of "validation of analytical methods for cleaning". Discuss the keys to method validation. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) What are LOD and LOQ? Explain its determination methods. (5)

7) Explain objective and advantages of factory acceptance test (5)

8) Explain the pharmaceutical water system validation life cycle. (5)

9) Explain the types of validation. (5)

10) Explain the computer system life cycle approach for a pharmaceutical industry (5)

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Question Paper

Exam Date & Time: 06-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Quality Assurance
MPharm Semester 2 - End-Semester Examination May 2019
Date : 06/05/2019

Audits and Regulatory Compliance [PQA-MQA203T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Discuss in detail about management of audit, roles and responsivities of an auditor and auditee (10)

2) Discuss in detail about role of quality systems and audits in pharmaceutical manufacturing environment. (10)

3) Prepare a detailed audit checklist for sterile dry production and packaging. (10)

4) Explain the importance of cleaning and sanitizing schedules and related documentation systems in microbiology laboratories (10)

5) a. Write about the treatment methods used in Effluent Treatment Plant. (10)
b. Write the audit checklist for Effluent Treatment Plant

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Classify the deficiencies in an audit and explain the impact of major deficiencies on the regulatory inspection (5)

7) Discuss in detail about importance of cGMP regulations on controlling quality Systems (5)

8) Discuss in detail about points to be considered during preparation of a capsule production facility audit check list (5)

9) Discuss in detail about sample flow in microbiology lab as per the regulatory Requirement (5)

10) Give a comparative chart for HVAC parameters in sterile and non-sterile area. (5)

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Question Paper

Exam Date & Time: 08-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Quality Assurance
MPharm Semester 2 - End-Semester Examination May 2019
Date : 08/05/2019

Pharmaceutical Manufacturing Technology [PQA-MQA204T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Discuss the levels and steps of production planning? (10)

2) Explain the quality challenges of prefilled syringe, needle free injection and large volume parenteral. (10)

3) What steps should be taken to improve the efficiency of material handling in pharmaceutical industry? (10)

4) Enlist and explain different types of glasses intended for pharmaceutical manufacturing. (10)

5) Which PAT tools should be implemented to enable the development of robust manufacturing processes? (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) List various forms required to obtain the wholesale and distribution license of drugs in India. (5)

7) Write a note on form, fill, seal technology. (5)

8) How pan variables affect the quality of tablet coating? (5)

9) Discuss the tests for plastic containers intended to use in the packaging of non-injectable preparations. (5)

10) Write a note on control strategy used in the QbD approach. (5)

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